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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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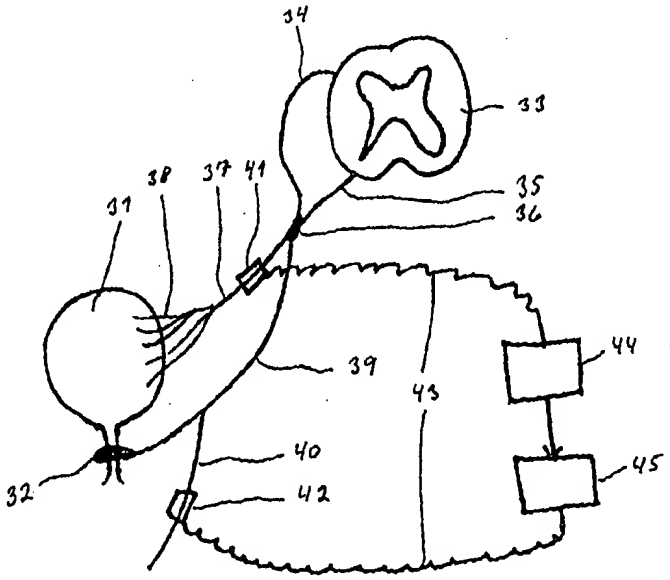
(54) Title: A METHOD TO CONTROL AN OVERACTIVE BLADDER



(57) Abstract

This application concerns a method to control an overactive bladder and to estimate bladder volume, comprising an implanted sensor, which sensor comprises at least one nerve electrode to sense electrical signals, means for stimulation of nerves to inhibit detrusor contraction, an electronic unit to detect events from nerve signals and generate electrical pulses for stimulating nerves. The object of the invention is treatment of involuntary loss of urine (incontinence) due to involuntary detrusor contractions (detrusor overactivity). Another object of the invention is estimation of bladder volume. This finds particular application in patients who use aids to empty their bladder e.g. intermittent catherisation or electrical stimulation.

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A method to control an overactive bladder.

This application concerns a method to control an overactive bladder and to estimate bladder volume, comprising an implanted sensor, which sensor comprises at least one nerve electrode to sense electrical signals, means for stimulation of nerves to inhibit detrusor contraction, an electronic unit to detect events from nerve signals and generate electrical pulses for stimulating nerves.

US 4,406,228 discloses a system that purportedly conditions pelvic floor musculature by means of neurostimulation for the purpose of controlling urinary loss. Such system includes stimulation apparatus for applying electrical pulses to electrodes implanted in the abdominal region or to a plug positioned in an anus. The plug contacts the spincter muscle of the anus for the alleged purpose of inhibiting bladder contraction in response to excitation of the plug.

In this way the bladder volume is not measured, which can lead to bladder over distensions, and can lead to bladder rupture.

The storage phase of the micturition cycle requires a stable bladder with high compliance (i.e. a relaxed bladder) and closed urethral outlet. However, due to the feedback system the bladder may easily become unstable. Any stimulus that elicits a small burst of impulses in the mechanoreceptor afferents, such as coughing and jumping may trigger an involuntary micturition reflex and cause urine leakage. To prevent this from happening the neural control system is equipped with several inhibitory circuits, both at spinal and supraspinal levels, which prevent the detrusor muscle to contract. However, these inhibitory circuits are susceptible to a variety of neu-

rologic disorders. Therefore patients with neurologic disorders frequently suffer from urinary incontinence due to involuntary detrusor contractions.

The impaired storage function could in principle be improved by methods that decrease the sensitivity of the bladder afferents, decrease the activity of the bladder efferents or increase the bladder volume/capacity. Available treatment options are therefore: surgical augmentation of the bladder [Sidi et al., 1990], surgical deafferentation of the bladder [Koldewijn et al., 1994], the use of anticholinergic drugs and the use of intravesical capsaicin [Wiart et al., 1998].

Bladder inhibition by electrical stimulation has been described before [e.g. Vodušek et al., 1988; Wheeler et al., 1992] but only continues stimulation was used, e.i. stimulation is permanent except during voiding.

Reff

Add: T. Lefurge, E. Goodall, K. Horch, L. Stensaas, and A. Schoenberg, "Chronically implanted intrafascicular recording electrodes," *Annals of Biomed. Eng.*, vol. 19, pp. 197-207, 1991.

Add: J.N. Sengupta, G.F. Gebhart, "Mechanosensitive properties of the pelvic nerve afferent fibres innervating the urinary bladder of the rat," J. Neurophysiol., vol. 72, pp. 2420-2430, 1994.

The object of the inventions is:

1) treatment of involuntary loss of urine (incontinence) due to involuntary detrusor contractions (detrusor overactivity)

2) estimation of bladder volume. This finds particular application in patients who use aids to empty their bladder e.g. intermittent catherisation or electrical stimulation.

The invention finds particular application in patients where the involuntary detrusor contraction is associated with a neurologic disorder.

Treatment of detrusor overactivity and extimation of bladder volume can be achieved by a method as described in the first paragraph using a closed loop stimulation system to allow event driven inhibition of the bladder where stimulation is only applied when an undesired bladder contraction occurs, and an implanted sensor comprising at least one nerve electrode to sense electrical signals from nerves innervating the bladder. Sensing electrical signals related to mechanical bladder activity via said sensor, and detecting the onset of a bladder contraction and estimation of bladder volume using signal processing methods, and activating an inhibitory neural circuit by stimulating afferent nerve fibbers, in response to detection of the onset of a bladder contraction.

By this method no nerves has to be cut, and no irreversible surgery has to be done. Stimulation of neural tissue only takes place when needed, and the volume of the bladder is monitored. The present invention uses electrical stimulation to inhibit the bladder. Inhibition of the bladder by electrical stimulation is possible since, besides the mentioned neural inhibitory circuits, additional spinal inhibitory circuits exist to prevent involuntary leakage during e.g. defecation, coitus and physical activity. Activation of the afferent path of these neural circuits has two effects: they activate the in-

hibitory sympathetic neurones to the bladder and they provide central inhibition of the preganglionic detrusor-motoneurons through a direct route in the spinal cord. These additional inhibitory reflexes are not suppressed during micturition, which means that they are quite capable of interrupting a detrusor contraction. Activation of these reflexes by electrical stimulation is a non-destructive alternative method for patients who are refractory to drugs, cannot tolerate the side effects or for other reasons do not accept a drug treatment.

Primalarythe recorded nerve signals comes from afferents innervating mechanoreceptors located in the bladder wall. By detecting the onset of the bladder contraction the stimulator could be activated only when contraction occurs, and continuos stimulation is not necessary. This minimises the risk of neural damages due to the stimulation. In addition, if the patient can sense the stimulation, the duration of stimulation should be minimised to minimise the discomfort.

The step of implanting a sensor might comprise the step of implanting a nerve cuff electrode. The cuff electrode has been used successfully in other applications and has been shown to be safe for human implants.

The step of implanting a sensor might comprise the step of implanting an intrafasicular electrode [Lefurge et al., 1991]. The intrafasicular electrode is flexible and smaller, and might be preferred in locations where limited space is available.

The electrodes can be used to detect efferent or afferent nerve activity. The same electrode could be used to record both types of nerve signals.

The electrode can be placed on a nerve that contains afferent nerve fibres innervating mechanoreceptors located in the bladder. In this way information about the status of the bladder can be obtained .

The electrode can be located at the intradural or extradural dorsal sacral nerve roots. In this way the electrodes can be placed at a mechanical stable position, and the nerve roots are relatively long, which enables easy placement of electrodes.

The electrode can be placed on a nerve that contains efferent nerve fibres innervating the bladder, so bladder activation can be monitored.

The electrode can be located at the intradural or extradural ventral sacral nerve roots. In this way the electrodes can be placed at a mechanical stable position, and the nerve roots are relatively long, which enables easy placement of electrodes.

The electrode might be located at at least one of the preganglionic pelvic nerve branches and postganglionic nerve branches. In this way nerve signals from the bladder can be recorded more selectively without contamination with signals from other organs.

Preferably two different nerve signals can be used to detect a detrusor contraction, where the first signal comes from afferent nerves innervating the bladder, and the second signals comes from efferent nerves innervating the detrusor muscle. In this way the detrusor contraction can be detected more reliable.

Activating a neural circuit that inhibits the bladder contraction can be done by stimulating afferent nerve fibres, innervating mechanoreceptors, located in the glans of the penis or clitoris. In this way an ongoing detrusor contraction can be aborted or stopped and leakage of urine will be prevented.

The bladder volume can be derived from the amplitude of the recorded afferent signal. By measuring of the bladder volume the patient can be informed about his/her bladder volume.

The bladder volume can be derived from the time between 2 consecutive detrusor contractions. By measuring of the bladder volume the patient can be informed about his/her bladder volume.

The bladder volume can be derived form both the amplitude of the recorded nerve signal and the time between 2 consecutive detrusor contractions. This way the bladder volume can be estimated in a more reliable way.

In the following the invention will be detailed described partly with reference to drawings.

Fig.1 shows a block diagram of event driven stimulation system to treat an overactive bladder.

Fig. 2 shows a block diagram of a bladder volume monitoring system.

Fig. 3 shows schematically how the invention is applied.

Mechanoreceptors located in the bladder wall act as tension receptors and respond in graded fashion to increases in bladder volume and intravesical pressure [Sengupta and

Gebhart, 1994]. It has been shown that a close relationship between afferent nerve activity and the pattern of intravesical pressure changes is best observed when the activity of many afferent nerve fibres is summed. Sensor 14 comprises an implantable nerve cuff electrode. This type of electrode surrounds the selected nerve in close proximity so currents generated by the nerve fibres result in sufficient large voltage differences in the volume within the cuff so that they can be detected by the electrode. However, other electrode configurations such as intrafasicular electrodes could also be used to detect the efferent nerve activity. The electrode needs to be placed on a peripheral nerve 15 that contains afferent nerve fibres innervating mechanoreceptors located in the bladder. Possible locations for the electrode are therefore: intradural dorsal sacral nerve roots (S2-S4), extradural sacral nerve roots (S2-S4), preganglionic pelvic nerve branches and postganglionic nerve branches. An alternative method to detect a bladder contraction is to record from the efferent nerve fibres that innervate the detrusor muscle. An increase in the efferent signal results in a detrusor contraction so an increased efferent signal indicates a detrusor contraction. Possible locations for the electrode to record efferent signals from peripheral nerve 15 are: intradural ventral sacral nerve roots (S2-S4), extradural sacral nerve roots (S2-S4), preganglionic pelvic nerve branches and postganglionic nerve branches.

The output of the sensor 14 is passed through a circuit 13 that includes an amplifier and a filter. The output of circuit 13 is passed to circuit 10, which contains a detection algorithm that allows the detection of the onset of a sudden rise in intravesical pressure or a detrusor contraction. The detection algorithm takes place in a signal processor 10, which will pass a trigger signal to

stimulator 11 when it detects such a pressure rise. The stimulator 11 includes one or more electrodes placed on peripheral sensory nerves 12. The stimulator 11 produces, in response to the trigger signal from circuit 10, an electrical potential difference, which will result in an electrical current through the electrode and adjacent nervous tissue. A rapid change in this electrical current activates or stimulates nerve fibres causing the production of action potentials in peripheral nerve 12. It has been shown that activation of afferent nerve fibres, innervating mechanoreceptors located in the glans of the penis or clitoris, has a strong inhibitory effect on the bladder. To obtain the desired effect of bladder inhibition upon stimulation the afferents should be stimulated somewhere along their course from mechanoreceptors to the sacral spinal cord. This means that possible locations for the electrode to be placed on peripheral nerve 12 are: dorsal penile/clitoris nerve, pudendal nerve, extradural sacral nerve roots (S2-S4) and intradural dorsal sacral nerve roots (S2-S4).

A system for monitoring the bladder volume is shown in FIG.2. Mechanoreceptors located in the bladder wall act as tension receptors and respond in graded fashion to increases in bladder volume and intravesical pressure. It has been shown that a close relationship exist between afferent nerve activity and bladder volume. In addition, bladder volume could be estimated from the time between two consecutive hyperreflexic bladder contractions since the number of contractions per time unit is proportional to the bladder volume. The preferred nerve electrode 25 for this purpose is an implantable nerve cuff electrode, although other electrode configurations could also be used. The sensor 25 comprises an electrode, which needs to be placed on a peripheral sensory nerve 26 that contains afferent nerve fibres innervating mechanoreceptors

located in the bladder. Possible locations for the sensor 25 are therefore: intradural dorsal sacral nerve roots (S2-S4), extradural sacral nerve roots (S2-S4), preganglionic pelvic nerve branches and postganglionic nerve branches. Sensor 25 could be the same one as sensor 14 so the systems of FIG.1 and FIG.2 share the same electrode.

The output of the sensor 25 is passed through a circuit 24 that includes an amplifier and a filter. The output of circuit 24 is passed to signal processing unit 20, which contains an estimation algorithm that allows estimation of bladder volume. If the estimated volume exceeds the volume threshold then a trigger signal will be passed to transmitter 21. Upon receiving a trigger, transmitter 21 sends a signal to receiver 22 using radio waves. Receiver 22 is placed outside the body and will, upon receiving a signal from transmitter 21, pass a signal to actuator 23. Actuator 23 will alert the user that the bladder volume exceeded the volume threshold. Various devices could be used as actuator such as a buzzer, a vibrator, etc.

Fig. 3 shows in detail the elements of the invention. A Bladder 31 with a closing mechanism comprising a sphincter 32 together with the innervating peripheral nerves, which comprises 34 intradural dorsal sacral root 34, intradural ventral sacral root 35, extradural sacral root 36, Preganglionic Pelvic nerve 37, Postganglionic pelvic nerve 38 and Pudendal nerve 39. In addition the dorsal penile/clitoral nerve 40 is shown. These nerves relay information to and from the spinal cord 33. A recording electrode 41 senses information from the nerves 37, and electrical information is transmitted through an electrode lead 43 to a signal processing unit 44, which is connected to a stimulator 45. Signal from stimulator 45 is transmitted through an electrode lead 43 to a stimulation electrode 42, which stimulates nerve 40.

10 Signal processor
11 Stimulator
12 Peripheral sensory nerve
13 Amplifier
14 Sensor
15 Peripheral nerve

20 Signal processor
21 Transmitter
22 Receiver
23 Actuator
24 Amplifier
25 Sensor
26 Peripheral sensory nerve

31 Bladder
32 Sphincter
33 Spinal cord
34 intradural dorsal sacral root
35 intradural ventral sacral root
36 extradural sacral root
37 Preganglionic Pelvic nerve
38 Postganglionic pelvic nerve
39 Pudendal nerve
40 Dorsal penile/clitoral nerve
41 Recording electrode
42 Stimulation Electrode
43 Electrode lead
44 Signal processing unit
45 Stimulator

Claims

1. A method to control an overactive bladder and to estimate bladder volume, comprises: an implanted sensor, which sensor comprises at least one nerve electrode to sense electrical signals,

means for stimulation of nerves to inhibit detrusor contraction,

an electronic unit to detect events from nerve signals and generate electrical pulses for stimulating nerves,

characterized in,

that stimulation is only applied when a bladder contraction occurs,

that the implanted sensor comprising at least one nerve electrode to sense electrical signals from nerves innervating the bladder,

said method comprises the step of:

a) sensing electrical signals related to mechanical bladder activity via said sensor,

b) detecting the onset of a bladder contraction and estimation of bladder volume using signal processing methods,

c) activating an inhibitory spinal reflex by stimulating afferent nerve fibres, in response to detection of the onset of a bladder contraction,

using a closed loop stimulation system to allow event driven inhibition of the bladder.

2. A method of claim 1, **characterized in**, that detected nerve signals primarily comes from afferents innervating mechanoreceptors located in the bladder wall,

3. A method of claim 1 or 2, **characterized in** that the step of implanting a sensor comprises the step of implanting a nerve cuff electrode.

4. A method of one of the claims 1-3, **characterized in**, that the step of implanting a sensor comprises the step of implanting a intrafasicular electrode.

5. A method of one of the claims 1-4, **characterized in**, that the electrodes is used to detect efferent or afferent nerve activity.

6. A method of one of the claims 1-5, **characterized in**, that the electrode is placed on a nerve that contains afferent nerve fibres innervating mechanoreceptors located in the bladder.

7. A method of one of the claims 1-6, **characterized in**, that the electrode is located at the intradural or extradural dorsal sacral nerve roots.

8. A method of one of the claims 1-5, **characterized in**, that the electrode is placed on a nerve that contains efferent nerve fibres innervating the bladder.

9. A method of one of the claims 1-5 and 8, **characterized in**, that the electrode is located at the intradural or extradural ventral sacral nerve roots.

10. A method of one of the claims 1-5 and 6 and 8, **characterized in**, that the electrode is located at least one of the preganglionic pelvic nerve branches or postganglionic nerve branches.

11. A method of one of the claims 1-10, **characterized in**, that 2 different nerve signals is used to detect a detrusor contraction, where the first signal comes from afferent nerves innervating the bladder, and the second signals comes from efferent nerves innervating the detrusor muscle.

12. A method of one of the claims 1-11, **characterized in**, activating neural circuits that inhibit bladder contraction by activating an inhibitory spinal reflex by stimulating afferent nerve fibres, innervating mechanoreceptors located in the glans of the penis or clitoris.

13. A method of claim 12, **characterized in**, that the stimulation electrode is located at a dorsal penile/clitoris nerve, or a pudendal nerve, or a extradural sacral nerve root or a intradural dorsal sacral nerve root.

14. A method of one of the claims 1-13, characterized in, that the bladder volume is derived from the amplitude of the recorded nerve signal.

15. A method of one of the claims 1-14, characterized in, that the bladder volume is derived from the time between 2 consecutive detrusor contractions.

16. A method of claim 14 or 15, characterized in, that the bladder volume is derived form both the amplitude of

the recorded nerve signal and the time between 2 consecutive detrusor contractions.

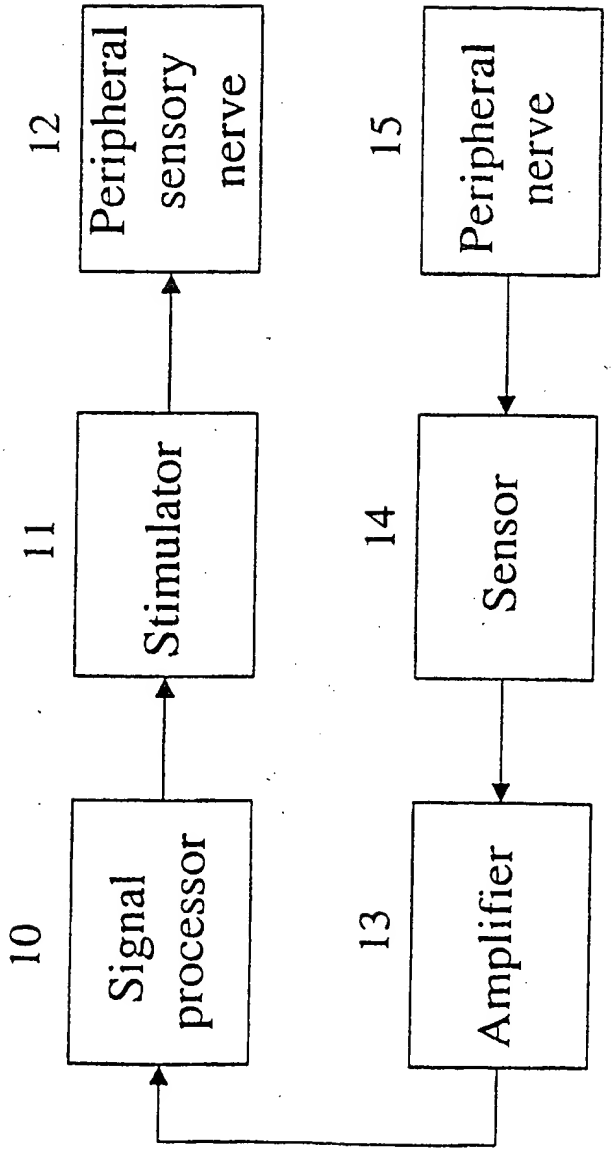

Fig. 1

Bladder patent

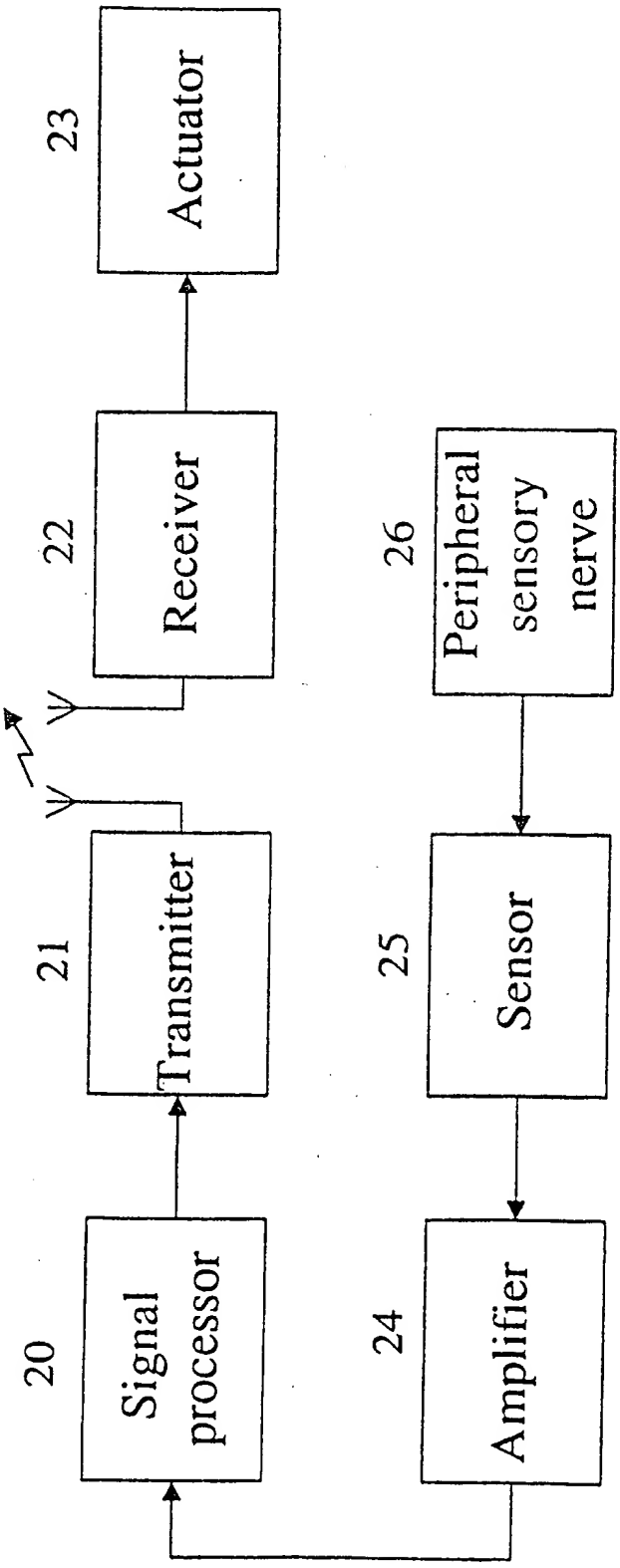

Fig. 2

Bladder patent

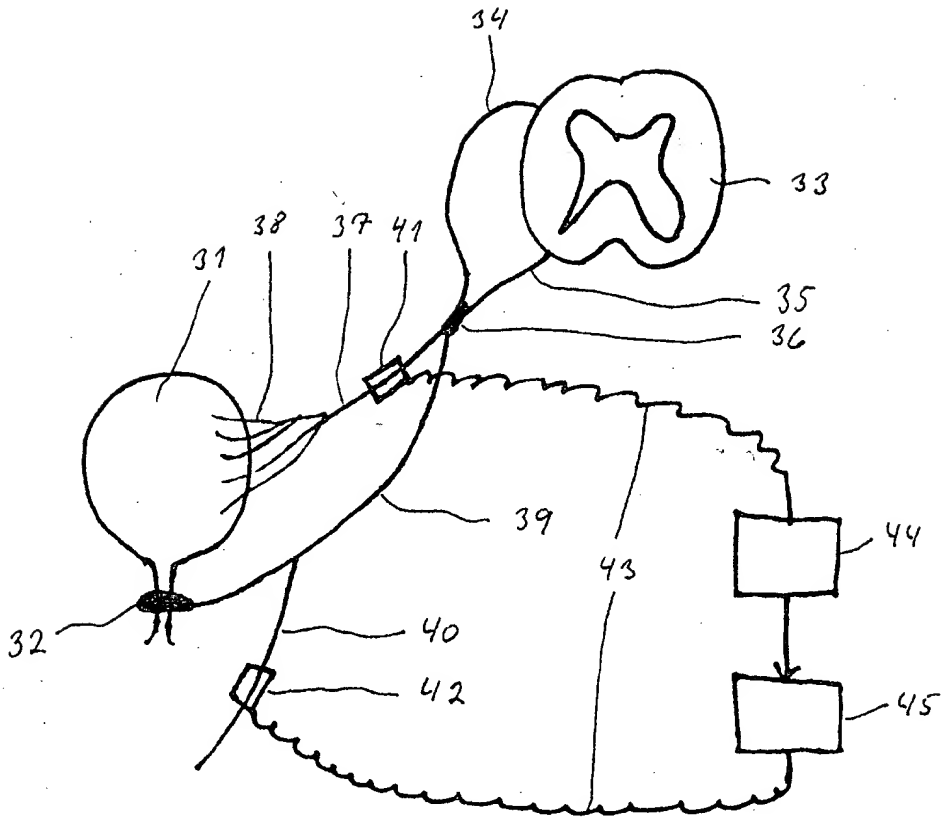

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00589

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4607639 A (E.A. TANAGHO ET AL.), 26 August 1986 (26.08.86), column 2, line 3 - line 11; column 7, line 59 - line 64	1-16
D,Y	Journal of Neurophysiology, Volume 72, No 5, November 1994, J.N. Sengupta et al., "Mechanosensitive Properties of Pelvic Nerve Afferent Fibers Innervating the Urinary Bladder of the Rat" page 2420 - page 2430	1-16
A	WO 9516491 A1 (THOMAS JEFFERSON UNIVERSITY), 22 June 1995 (22.06.95), abstract, table	1-16

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search	Date of mailing of the international search report
26 January 2000	16 -02- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nikolaj Hautaviita/AE Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK99/00589

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-16
because they relate to subject matter not required to be searched by this Authority, namely:

See next sheet.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Claims 1-16 relates to a method of treatment of the human or animal body by surgery or by therapy diagnostic methods practiced on the human or animal body/ Rule. 39.1.(iv). Nevertheless, a search has been executed for these claims. The search has been based on the device described in the method.

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/DK 99/00589

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4607639 A	26/08/86	US 4703755 A	03/11/87
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		SE 0245547 T3	
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		CA 2178904 A	22/06/95
		EP 0744980 A	04/12/96
		JP 2810793 B	15/10/98
		JP 9507401 T	29/07/97
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